UNITED STATES DISTRICT COURT

DISTRICT OF NEW JERSEY - TRENTON

MEDEVA PHARMA SUISSE A.G., et al.,	:	Docket No.: 07-CV-5165-TJB
	:	Trenton, NJ
Plaintiffs,	:	
	:	November 23, 2010
vs.	:	
	:	
ROXANE LABORATORIES, INC.	:	
	:	
Defendant.	:	

TRANSCRIPT OF CONFERENCE HEARD BEFORE
THE HONORABLE TONIANNE J. BONGIOVANNI, U.S.M.J.

TRANSCRIPT ORDERED BY:

FRITZ SAMMY, PARALEGAL
(GIBBONS, PC)

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I N D E X

11/23/10

THE COURT: We're here in Medeva vs. Roxane. Can I have appearances?

MS. LONGSTAFF: Carrie Longstaff on behalf the plaintiffs. And I'd like to introduce the Covington folks.

MR. SIPES: Your Honor, Mr. Sipes from Covington and Burling on behalf of the plaintiffs, Medeva and Medeva and Warner Chilcott. And here with me is my colleagues, Paul Ainsworth and Megan Keane.

THE COURT: Didn't want to let -- Ms. Megan what?

MS. KEANE: Keane.

THE COURT: You didn't want to let Ms. Keane sit at the table with you, or she didn't want to sit at the table with you.

MR. SIPES: I didn't want to ask her.

THE COURT: She certainly, if you want to scoot around, you're more than welcome. If you're content back there, that's fine. Great. Thank you. You can be seated.

MR. OLINKSY: Good afternoon, Your Honor. Mark Olinsky, O-L-I-N-S-K-Y from Sills Cummis and Gross, and joining me is Mr. Galbaith, who you're familiar with, on behalf of Roxane.

THE COURT: Yes. This is a familiar panel to me. Good afternoon.

I have some very discreet pointed questions. I, obviously, have the benefit of the briefing in this case. And

I didn't bring you in here just for the exercise of it. So, if you bear with me, we should be able to get through this fairly swiftly. I don't think it will be as swift as perhaps the Supreme Court of Third Circuit argument. I don't have the red, yellow lights up here, and I'm not limiting anyone to 15 minutes, certainly. But hopefully, we won't be here anywhere near the wee hours of the evening.

(REDACTED)

And if I could turn to Roxane, and I have a couple of questions. So, let me just string them along for you.

First is -- uh, oh.

MR. OLINSKY: I'm okay. I have to answer your question.

THE COURT: First is why shouldn't Roxane and -- why shouldn't this lot number have been considered part of Roxane's Endo product? And tying that into how come it was never identified on your privilege log?

And I do recognize that you have provided a explanation in your papers relating to tying it into expert discovery and that it didn't need to be produced. But I just want to clarify if that's the only answer you're sitting with.

And if so, what happens if I disagree with you on that point and find that it actually falls outside of the

tying it solely into the expert production and that you had a separate obligation to, at least, identify the existence of the product, perhaps not the testing, etcetera, but, at least, the existence?

So, let's start there.

MR. GALBAITH: I think the advance have overtaken this motion, Your Honor. This -- to bring everybody up to speed on what's happened here.

(REDACTED)

Nobody is referring to this as -- anymore. Our expert is not relying on it. Their expert is not relying on it.

(REDACTED)

. But it's -- it's no longer really part of the case. So, what happens to it, I don't think it's -- frankly, I don't think needs to be decided, at this point.

(REDACTED)

THE COURT: And what were you thinking or contemplating might happen as a result of that experiment? What were you either hoping for or trying to negate?

MR. GALBAITH: The -- well, trying to find out the answer. The way the -- the experiment was supposed to work, the product would be ingested by a -- a subject of experimental -- a volunteer, a paid volunteer. And it would go into that volunteer's stomach and go into his medicine track.

(REDACTED)

And what we hoped it would show was exactly the fate of the tablet when -- when the tablet disintegrated and released its contents.

(REDACTED)

And that's an issue in this case. Where does this tablet disintegrate in the digestive tract? That is the issue on infringement.

THE COURT: Unfortunately, I know that, ad nauseam.

MR. GALBAITH: You've heard that before. But -- and the experiment was designed to test the hypo-- or to determine where that occurred.

(REDACTED)

That's why we came back to Your Honor to ask for more time to do more experiments and that's why we offered to stay off the market for an extended time the first time because our experiment failed. That's what happened to it.

There's no question, however, but for that reason, I

think it's a -- a really moot point.

THE COURT: Let me have you hold that thought. Is it a moot point? And all I need is almost a yes, or no.

MR. SIPES: We don't believe it's completely moot, Your Honor. Some of the harm to us has been eliminated by their recognition now that it's not representative of their product, which is not where we started this.

There is, however, some lingering harm that -- that we do think maintains it's relevance to this motion. A lot of what's going on here, Your Honor, is a considerable amount of after the fact revision.

(REDACTED)

When they -- and we repeatedly inquired during this time how many -- tell us all of the batches that -- released as to how many you've made. They never revealed this batches.

(REDACTED)

THE COURT: Let me, Mr. Galbaith, maybe you can sit for one second --

MR. GALBAITH: Sure.

THE COURT: -- because I thought this would be a

tight question that I have. But tell me you just said that it doesn't eliminate the harm completely. Tell me why not.

MR. SIPES: Well, because the consequence of it being sprung on us is that we had to work at considerable expense, cost and expense, over the Christmas and New Years holiday a year ago to actually determine what we found out but, at that point, they were representing the exact reverse, which was this was not at all representative --

THE COURT: So, is this solely and I'm not minimizing cost and distraction, but is this solely a cost issue for you versus substantive? Is there a substantive issue for you?

MR. SIPES: The -- the only substantive issue -- assuming that we are now in agreement, that this is not representative. That they are no longer representing that this is representative of the Endo product, then -- then --

THE COURT: Let's take a break. Are we agreeing to that, Mr. Galbaith?

MR. GALBAITH: Yes, Your Honor. We said that almost a year ago.

THE COURT: Okay.

MR. SIPES: So, assuming then -- the only issues are the costs involved and the fact that we think it shows in connection with the other documents that were lost the fact that there has been a distortion of discovery that prejudiced

us. This would have been tried last March as -- that product being represented -- representative of their Endo product, were we not able with our experts over the Christmas and New Years holiday to discover what they had not allowed us to investigate previously, which is the fact that it was not representative of their product.

THE COURT: And so, what's the remedy?

MR. SIPES: Well, the -- we think the remedy is in the context. We think this shows in the context with the other documents that were destroyed that there has been a serious aversion of factual discovery in this case.

And we think this shows both the fact that it's been ongoing and that we've been prejudiced. This shows the type of harm that may result.

The other -- in terms of the secret batch itself, that's the only relevance, Your Honor, other than the cost because we were able to -- to discover on our own that it was not representative and they have now acknowledged that.

THE COURT: Okay. I don't want to then belabor this point too much but I do think it is important for me to have, I think, the -- to have the rest of these questions, at least, perhaps slightly addressed, not in as much detail, give you the chance for whatever spill over effect, it might have, Mr. Galbaith, on any of the other questions that I have.

So, let me ask you, just to talk to me a little bit

about, again, let's assume that I've -- I find that the -- that this -- the fact that this batch existed should have been disclosed and contained in -- in some -- at least, in some privilege log and that it's not protected by tying it to an expert. Are there any cases that you can point to that stand for that proposition?

And again, I'm not talking about any of the testing of the product, but just the fact that the product exists.

MR. GALBAITH: Well, I mean, we cited cases that show that this is classic work product. They've cited no cases to show that it isn't. We cited -- we cited a Third Circuit case that says that work product like this does not -- work product is not -- is generated after the case starts is not something you have to schedule.

THE COURT: And that's the case that they say that in a footnote, as I recall.

MR. GALBAITH: It's the Grider (phonetic) case --

THE COURT: It's the Grider case. Okay. But then tell me how is this case different from the Feacher case, phonetic F-E-A-C-H-E-R, out of New York. I recognize it's a District Court case, but --

MR. GALBAITH: Well, I guess I -- typically, Your Honor, I've just never been in a case where you have to schedule your work product as a -- certainly, the plaintiff never scheduled any of their ongoing work product in this case

while it was being generated.

We have -- they did a lot of experimental work of their own. None of that was ever put on a privileged log. And the same with us. The experimental work that was done on behalf of our client that we did was not put on a privileged log.

I've never been in a case, frankly, where anyone did that. And I think that's what the Third Circuit case tell us.

(REDACTED)

MR. GALBAITH: **(REDACTED)** . This -- this was -- there was -- there was a motion practice in this case where the plaintiff asked Your Honor to order us to disclose it to the FDA. And Your Honor said, we didn't have to. That's -- that's the context.

(REDACTED)

But in any event, neither side here has given ongoing updates of its work product. Every time I write a letter to the client, I don't schedule in a log and send it off to -- to the other side and they have not been doing the same thing with us.

The correspondence that they've had with their experts, they have not sent to us. We have not done the same thing.

THE COURT: Well, in part, you have a separate agreement dealing with the experts. And I think that communications with your client are very different than the existence of a -- a product.

MR. GALBAITH: But work product is work product whether it is done by an expert or a client. That's what the Rule says. It says by or for a party.

THE COURT: No. I'm not saying it's not work product. The question is why it's not -- the log is just not updated and identified. And -- and it's -- this is to me is a very different type of -- it's not a document, it's a item than a -- a letter or a correspondence that's just sent to a client in the normal course keeping them updated.

MR. GALBAITH: The -- first of all, the -- the -- under the Third Circuit law, as we read it, we don't have to do that.

Secondly, putting a -- a logging material like this

on the -- on a privileged log reveals the work product. It does reveal the kind of experiments we are doing. It reveals our mental process -- it essentially tells them what our work product is before the time required under the schedule to reveal that work product.

We don't think we're obligated to do that. We know of no case law or order that requires us to do that. Certainly, they didn't do that on our behalf.

MR. SIPES: Your Honor, if I may, just very quickly. The context here is very important. First of all, we're not aware of any cases that have suggested that work product can be used to hide the actual existence of materials.

In fact, my understanding of the law is the exact reverse. That one cannot hide the existence of materials through work product even to simply try to shield from just what your materials are.

In this case, in particular, remember there was a dispute from the very beginning in this case about the availability of delayed release -- product made by defendants.

When the case began, they had only one lot and it was expired. And they insisted that before they produce it to us, that we would agree not to do human testing without Court agreement because of that. There has been a dispute from the beginning about the availability of this material.

We asked them several times throughout the course,

which lot -- what lots were manufactured at least for --

Work product doesn't justify giving a false answer to those questions. If -- what --

THE COURT: Or even just an omission. I think, as I understand Mr. Galbaith, his position is that this -- the existence of the product itself is considered work product and that because it's -- it is work product, that he didn't have to put it on a log because that would have defeated the purpose and you would know.

MR. SIPES: But, of course --

THE COURT: And you disagree.

MR. SIPES: Even in the interrogatories -- they could have said, there may be additional batches made at Counsel's request whose production would be protected by work product. And then, we could have this discussion about whether or not, in fact, they are produced.

They unilaterally resolved it by not even saying that. If Mr. Galbaith had said in the interrogatory responses, and the 30B6 deposition on this point, the witness had said, and that the chart they had brought had said, there may be additional batches protected by work product that was made at Counsel's request.

Then we could have aired the issue and decided then whether we're entitled to factual discovery. But to -- to hide even the issue, which -- this is a very unusual assertion

of work product privilege.

And -- and it certainly wasn't the way that the product was treated when they tested it.

(REDACTED)

But we don't need to get into the merits, because the merits were foreclosed.

THE COURT: And -- and actually, thank you. I know we got off track a second.

(REDACTED)

So, for whatever that's worth, that's what -- that's where I was going with that question.

But let me ask you your position about this before and after the complaint distinction.

MR. SIPES: Well, both parties have really been producing materials that post date the complaint. In fact, one of the two lots of material that was produced was post complaint. There hasn't been a shield for material produced after. In fact, you know, they now have an ongoing promise to prod-- to continue produce their -- and their correspondence

with FDA.

But this is particularly important with regard to the test product. Because remember there was a limited amount of product available for testing. And there was a great concern about what material was actually represented in the Endo because the material that was available at the start of the case had expired.

And that was the reason why there was so much inquiry into when they made new batches. They knew that this was at issue. This question of what material is available to test.

If they want to assert work product on the actual material itself, people have a right to serve work product even if they may not have, in the end, to be found work product. But they have to tee up the issue in a way when both sides have a fair opportunity to contest it, where they know this is a disputed issue.

By doing what they did, they put it in a position where we didn't even know the issue existed of a lot of material that was purportedly work product. We had no opportunity. We asked specifically by interrogatory, by letter and by deposition for what lots had been made.

At a minimum, they have to put us on notice that they're not giving us a complete response and there may be other lots that they're asserting work product for.

And, of course, the consequence, it's clear why. Because when it gets sprung on us after factual discovery, there's a good chance that we won't be able to test it.

We were very fortunate. We have good experts in this case, who are real experts.

(REDACTED)

THE COURT: Can I assume the questions, any questions I might have about the human testing issue are really not of any moment here?

MR. SIPES: I don't think they're relevant to this motion, Your Honor.

THE COURT: All right. I'm switching gears. Let's turn to, I guess sort of from the beginning. The whole question of the retention policies. And I -- I want to make sure the time line. So, Mr. Galbaith, when do you claim that your client actually anticipated litigation in this matter?

MR. GALBAITH: I think we don't. We're not going to

argue that was before 2000-- that it was after 2002, Your Honor. I think that's when they started looking at this. And they had a policy in place that all documents in a -- related to a live file, that this was, are to be retained. That -- that was the company policy. And --

(REDACTED)

MR. GALBAITH: I think the date that the plaintiff's have argued for is February, 2002. And I'm making an objection to that.

MR. SPIES: I think the date we said originally is July 31, 2001. You have it exactly right, Your Honor.

(REDACTED)

THE COURT: What about that?

MR. GALBAITH: I don't know. That's -- that --

THE COURT: You should know. That's important.

MR. GALBAITH: Frankly, I don't think it's important because there was a policy that predates all of these policies

that goes way back. And to any time there was work done on a -- on a -- on a live product for Roxane, Roxane had a policy in place to retain documents --

THE COURT: But we don't have a litigation hold until '05.

MR. GALBAITH: That's correct, Your Honor. But we had a policy that -- that documents were not to be destroyed.

MR. SIPES: And, Your Honor, just to clarify, the litigation hold was 2007 after the Endo was filed.

THE COURT: Okay. But in any event, whether it's July 31st, or -- at -- at best, it's July 31st, at worse or vise versa, the earliest is July 31st. That's how I should characterize it. The latest -- would be February, 2002.

MR. GALBAITH: February, 2002.

THE COURT: '02. All right. Okay. Then let me ask, let me turn to Medeva, actually. So, Mr. Galbaith, you can get off your feet for a minute.

If we have the litigation hold, and it's put into place in July '07?

MR. GALBAITH: I think so. That's approximately right, Your Honor.

THE COURT: Okay. Then why is the retention policy, which I believe is attached to Roxane's response at HH insufficient?

MR. SIPES: There's -- there's a three fold answer

to that. First, let -- let me be clear on this retention policy that they've come in. That was produced on the day that they filed there sir reply. So, we had no opportunity to question any witnesses on that.

Our reading on it is that it's actually quite limited.

(REDACTED)

But without getting into a fight over what their memo means to them, we do know that many important development documents were not preserved.

(REDACTED)

Remember, as -- as you probably too well, this is a product that actually acts topically in the gastrointestinal tract. So, how it releases its release profile is critical to development of a generic product.

(REDACTED)

THE COURT: Okay. But, quite actually, that ties into another area of questions I have. Putting aside whatever

Roxane's obligations were on spoliation, did you go to Anapharm and attempt to obtain documents and -- and why wouldn't that be your responsibility, as well?

MR. SIPES: We didn't know of Anapharm's role until fact discovery was closed. They say -- the name Anapharm only appears twice in 90,000 pages of documents. So, it wasn't clear. We didn't understand what they had done until we were able to depose a number of their witnesses who were offered at the end of fact discovery.

So, we came to an understanding of Anapharm after fact discovery had closed.

THE COURT: But why not come to me and ask for relief because you folks certainly know how to do that if you -- if you were concerned about fact discovery ending, ask for the ability to issue a non-party subpoena if you think Anapharm may now be in the possession of documents that are relevant.

Because with spoliation, we always have a number of concerns. But at the end of the day, the idea is are you able to get in your hands information that you need to either prosecute or defend a case.

And while it may very well be that Roxane would still be held responsible for not having produced the documents and could be sanctioned for it's conduct, if you -- you can't just sit back and say, well, we didn't -- we didn't

look anywhere else because we didn't want to bother.

MR. SIPES: At that -- at that point -- there's -- there's two aspects to it. One, is that at that point, we didn't believe we had time even if we could get leave.

Number -- by this time, it's the late fall of 2009 with the case scheduled ordered for trial in 2010. We had sought other third party discovery in the case that had taken us more than a year to get documents. The -- the way it has worked is when we have served third party subpoenas in this case, Roxane's counsel, has also ended up representing those third parties. And it took us a year to get third party documents.

THE COURT: Where's Anapharm located? Do we know? Do you know?

MR. SIPES: Standing here today, I apologize, Your Honor. I don't know where Anapharm --

MR. GALBAITH: I believe it's an American company. One of the problems that we had with the other subpoenas is they were located in Europe.

MR. SIPES: So -- so we were concerned about time and candidly, preparing for trial in the case and going through expert discovery.

The other thing is our focus really is on what -- we think what's relevant here are the documents, which are missing, which is what did Roxane do with this information?

That is they reached a conclusion.

(REDACTED)

We think they set that up as their target for -- for that -- their product, which is directly relevant to the issues in the case.

But it's -- it's Roxane's documents that are directly relevant to the case, which is --

THE COURT: Well, I know one of the things that you're complaining about is the fact that you don't have the protocol. I think Roxane said in one of the questions I have for Mr. Galbaith, just so I'm clear on the answer, is I don't know whether they never had it or they had it and no longer have it.

And I guess for both of you folks, this is your business. Are protocols generally produced from, I call them, non-parties?

MR. SIPES: Your Honor --

THE COURT: Provided to you, I mean.

MR. SIPES: In my experience, the way the protocols worked is they're defined by the sponsor. So, in this case that would be Roxane, worked out with -- it's called a CRO, a contract research organization. So, the protocols worked out between them and they would preserve parties.

Typically, in the litigation, these protocols come out. We have protocols for other studies that were done,

later studies that were done. We even have protocols for the studies that were done by the experts.

THE COURT: The question that I have though is -- when I mean -- when I said, produce, I meant, you have now contracted. And in this case, they -- Roxane and Anapharm has this business arrangement. And is it in your experience the norm that Roxane as the contracting party would retain in it's files a copy of the protocol.

MR. SIPES: That's -- that --

THE COURT: Because frankly in other situations the parties who were doing all of the testing and all of the run down, don't -- do not necessarily provide the contracting party with all of that minutia of detail. I recognize the protocols different. But in your experience, in that, not in terms of litigation, but in terms of that business arrangement.

MR. SIPES: Yes, Your Honor. In my experience, the contracting party in working with the CR always retains the protocol.

THE COURT: Let me ask Mr. Galbaith that question.

MR. GALBAITH: That's not necessarily true. The -- this -- the way this was done was there is a contracting party, a fellow named, Kramer, who actually dealt first hand with Anapharm.

(REDACTED)

Nobody suppressed this evidence. They got it because Roxane produced it to them. There's no hiding of this study. Roxane -- the only reason they know about it is because it was in Roxane's files and Roxane provided it.

It's not clear from this record whether there ever was a protocol in Roxane's possession. But the point is that the study report --

THE COURT: Well, has -- I'm sorry, has anybody been asked that question at all in the -- in the depositions that you've taken?

MR. SIPES: Yes, Your Honor.

(REDACTED)

THE COURT: But the question also is whether it was ever in Roxane's possession.

MR. SIPES: The question was in there --

(REDACTED)

So, she testified that they would have had the protocol. I can give you the cite. It's exhibit six. It's the deposition of Ms. Erentz, at pages 56 to 57, beginning at line 56, line 23, and going to page 57, line 5.

THE COURT: Again --

MR. SIPES: She was a 30B6 witness.

THE COURT: I guess I come back to the -- the question is if Medeva, based on its general experience and then based on the testimony felt that there was a protocol. And if it was so crucial, why you didn't bother to make efforts to obtain that from Anapharm instead of just throwing up your hands and saying, well, Roxane has spoliated, if that's a word, and then, therefore, should be sanctioned.

MR. SIPES: Your Honor, I believe that what happened is that by the time we learned of this and appreciated it's significance, it was the fall of 2009. We were into expert discovery and rushing for trial. Pretty shortly thereafter we had sprung on us --

THE COURT: I know. But -- but, obviously, here it is the fall of 2010, and a lot has happened, including back in the spring the stipulation that they weren't going to launch. And that there was going to be a continuation. So, I guess I'm just concerned that when it now was clear -- when it became clear that we were going to have time that there wasn't any effort to even see if you could get this information.

So, the -- the real obvious -- if it's not obvious, I'll make it obvious. The practical obvious question I have is if you're jumping up and down about this information and saying it is so important, why you didn't try to get it from somebody else, namely Anapharm at any point since you became aware of it?

And I won't torture you anymore.

MR. SIPES: Thank you.

THE COURT: I understand your answer.

MR. SIPES: And I guess the other point, too, is by the time we actually were aware that they were going to seek a delay, we had already filed our motion seeking redress.

But -- but, Your Honor, I -- I take --

THE COURT: Mr. -- go ahead, Mr. Galbaith. Do you have something you want to say?

MR. GALBAITH: Your Honor -- the -- the report is -- first of all,

(REDACTED)

But that's -- other than that, the reports says what they did. The report says, we did this. We did this. We did this. That's the protocol they followed. It's in the report.

The protocol says, here's what we're going to do. The report says, here's what we actually did and here's the results that we got.

THE COURT: Do they ever differ? And you know we're talking inferences.

MR. GALBAITH: I don't know that they ever differ but what is important here is what the results were. And they have those results. Roxane produced them a long time ago.

And the only utility of those reports is to provide some basis for a motion.

(REDACTED)

And secondly, obviously, in early -- late 2009 and 2010, somebody at the plaintiff's office was spending an awful lot of time preparing these motion papers, which are double sided about two inches thick.

And, it seems to me, Your Honor's point is well taken, that if this was something important, either come to Your Honor to ask, or come to us to see if we can get it.

We never even heard about this issue until we saw this motion. Nobody mentioned to us that there was any problem with this Anapharm study or this Anapharm protocol.

THE COURT: Just getting back -- let's focus on the specific issue, getting back to the more generic issue regarding spoliation. Tell me, Mr. Galbaith, I didn't pursue

this before, but you mentioned that you didn't think you need a litigation hold earlier because the retention policy was sufficient. Why?

MR. GALBAITH: Well, I think it's not the question of whether it would have been a good idea or not a good idea to have a -- to have a direction from -- from counsel, don't throw anything away.

But, in fact, we're dealing with facts of a particular case here, not what's the best practice as far as a pharmaceutical company.

But we're doing in this case, there was a retention policy in place that covered this -- all these development documents. So, the people at Roxane were under direction, being a regulated company, to retain -- to retain the documents and not to destroy them.

And that policy -- the -- a copy of that policy was produced very early in the case. It wasn't just come with the -- the -- it didn't just come with the certified brief. It was produced early on -- in the first dep-- depose on.

But -- but, I mean there is no -- I don't think there's any inference that can be drawn from the fact that a formal litigation hold, a direction from counsel wasn't sent out until the case was filed.

THE COURT: No. I think in some of the papers you cite to a 2008 policy. But wasn't --

MR. GALBAITH: The policies go back --

THE COURT: We've been

MR. GALBAITH: -- we did go back and pull out the earlier ones and they're similar.

THE COURT: All right. Somewhat along the same vein of dealing with documents, and I had just a really basic question when I was reading all of the information about the emails and the digital discovery, the computer discovery, is as you folks are aware, under our rules of civil procedure and then specifically here in our local rules, referencing 26f and then local rule 26.1 -- 1d3, you're required to meet and confer.

This is a big area for all pharma cases. And you're required to -- to talk about what -- what you're going to be doing in terms of your computer discovery, your electronic discovery and whether or not you are, for example going to have your back up tapes preserved. And I understand that's one area that you had an agreement.

So, I am just a little perplexed as to why you didn't have something in place that from -- from the outset. And this case was filed in '07, and perhaps some of this information would have been caught up in that.

So, talk to me about, you know, what discussions you folks had, if any, regarding how you're going to preserve documents, computer -- digital documents.

MR. GALBAITH: There were discussion about -- about the -- the discovery, I guess it's called and there was an agreement reached, which is one of our exhibits. I have to dig it out. Bear with me.

THE COURT: Well, I know the back up tapes and the stipulation is referenced on page 15 of your briefs. But I don't recall where the -- if the -- where the actual e-discovery agreement is.

MR. GALBAITH: I apologize. I just don't remember where it is in -- in the pile of exhibits.

THE COURT: Welcome to my life.

MR. GALBAITH: I just have to find it, Your Honor.

THE COURT: Okay. But --

MR. GALBAITH: But there is a -- there was an agreement reached about how to handle e-discovery.

And, again, and here we are, have them having filing a motion after discovery is closed about suddenly complaining about the email production with nothing --

THE COURT: And I know one of the big things is this -- which I'm still learning, native format, different format, and you jinxed me because I repeatedly go through these conferences. And, knock on wood, I say, this is really not a huge issue for me. I might have people coming talking about search terms and their too broad and narrow them, and that sort of issue.

But, in terms of the actual preservation, and this bar in particular, has been wonderful about designating people and making sure that you know exactly what you want and whether the native format matters or whether you need the hard copy. And perhaps it's because you speak the same Geek language behind the scenes, so you understand it a lot better than I do.

So, I was a little disheartened to see that now I have my e-discovery dispute. And then, again, perplexed as to whey it wasn't really spelled out that -- regarding what the production would be.

But, you know what, Mr. Galbaith, you can actually get off the hot seat for a minute. Because one of the questions that I do have for Medeva is what harm, at the end of the day, again, what harm have you suffered by the fact that you only received some documents in one format?

MR. SIPES: Your Honor, we believe we're missing a wide swath of product development documents. The reason that this wasn't addressed in the initial stipulation is we did not imagine going in that there would be a six year development of this product during which there was no litigation hold.

And there are -- it is clear that there are documents missing.

(REDACTED)

We know that there are documents missing. One

of the Anapharm documents. Clearly, there are documents missing. The other is a lot of electronic files.

The project leader for this project, for development delayed -- delayed release -- at Roxane, is a fellow named Eric Spiller (phonetic).

(REDACTED)

THE COURT: Let me ask a time question. And I don't know if you have this in front of you. And, again, I recognize that in a vacuum it might seem naively obvious to me that this is an important issue. And if you -- I -- I would think that the outsets that you're asking your adversary about their litigation hold and their retention policy early on. And if that's done and you learn that there's a six year gap, why aren't you doing something to address that immediately with them and say, I have -- this is a red flag for me and I have some concerns.

So, I don't know if you can speak now to when you learned any of those --

MR. SIPES: What I'm worried, Your Honor, is that the witnesses that began the release -- and when we got the log to show when they began to anticipate litigation, when we began to learn of all these missing documents, it was late in fact discovery.

Many of the witnesses that they produced that bore on this issue were produced at the end of fact discovery.

THE COURT: You didn't get a dated litigation hold memo early on in document production?

MR. SIPES: I don't think to this day we have a litigation hold that I'm aware of.

THE COURT: That was just all testimonial?

MR. SIPES: Correct. And so, you know, we -- we simply felt -- we -- we were really blind sided with this at the end of the fact discovery. And then it became clearer and then as we went back and looked at it, how much material was missing. I mean this -- this product almost sprang out without any -- it's as if they created this product without really having a target.

And then we began to understand that's what's going on. And there are a lot of missing documents. Ordinarily, I would say, you wouldn't think you would need the back up tapes, that things would be preserved in anticipation of litigation.

This is an unusual case --

THE COURT: Okay. And so then let me ask Mr. Galbaith just why didn't we have a production of both the hard copy document and emails, as well as the electronic version or -- or just the electronic, which seems to me easier to produce?

MR. GALBAITH: The -- the -- Mr. Sipes incorrect about when the document protection was described to them.

Actually, the very first deposition was taken in the case was more than a year before fact discovery closed.

And that witness, Tina Carborino (phonetic), described all the searches that had been done of every witness, including Mr. Spiller.

Specifically, what had been done with respect to his files and what had been fast. So, it's not correct that they didn't know what the document production was like and what the documents -- how documents were searched before that.

This is the way Roxane chose to do the search. It was described in this deposition by Tina Carborino exactly what she did, the steps she took.

As far as we were concerned, as far as anybody ever told us, plaintiff's were okay with what was done. There was no complaint to us except the usual complaints about, you know, what about this project? What about that which we resolved either with Your Honor's help or -- or on our own.

But in terms of the way documents were obtained from Roxane and the way Roxane searched it's files and the way it produced the documents, we never heard a complaint about it until this motion was filed. And suddenly, it's -- it's a huge deal.

And with respect to what they've actually discovered in terms of missing emails, they found two.

THE COURT: Let me ask you on page 9 of their

opening brief, they outline a number of, as they characterize them, critical documents that they received only paper copies of and they go through them.

Do you -- are those documents still retained in the emails or have they been purged or written over?

MR. GALBAITH: The -- this -- are you referring to, Your Honor.

THE COURT: No. Well, I guess both, yeah. Above in the paragraph they give an example. But yes, so both -- both of those.

MR. GALBAITH: I don't know whether these -- these documents exist in electronic form. This was the form that was apparently easiest for Roxane to retrieve them from. This was the form we produced them in. This was the form that --

THE COURT: And your position is --

MR. GALBAITH: This was the form that was acceptable to plaintiff's throughout this case until after discovery closed and this motion was filed.

THE COURT: And your position is that all but two items have been produced and only two are missing, although I don't know how we determined --

MR. GALBAITH: The ones they -- they identified two because they prepared document production from an outfit called Quintiles (phonetic), which is a contract researcher that did clinical trials and documents produced from Roxane.

(REDACTED)

THE COURT: Okay. But I guess, how do they prove the negative? Because if they're missing, then how do we -- how are we certain that there are no other crucial documents that are missing because I think in your brief, you call them a stray email or two that were missing.

MR. GALBAITH: Your Honor, I can't -- nobody can prove the negative. We did a search, and this is what people were told to maintain in their files. And they maintained their files. We did the search. We produced what we found.

They can't prove the negative. We can't prove the negative. But to say that there are vast swaths of documents missing is just wrong.

We produced 80,000 pages of paper including thousands of emails and thousands of development documents, report after reports, 30 - 40,000 pages from the A and DA with -- with dozens of reports in it, development documents within the A and DA.

It's not like they don't know what this product was and how it was developed. They've got a mountain of information about this product --

THE COURT: Oh, but I know you folks are never satisfied with the mountain. Or you want a mole -- you have a mole hill and you want to create a mountain. But let's --

MR. GALBAITH: I think what they want to create is -- is -- is a -- is something different, Your Honor.

THE COURT: Let me ask though, mr. Galbaith, then --

(REDACTED)

MR. GALBAITH: Well, she -- I mean, she did her best, Your Honor, to determine that the -- the company had a -- even if the company had a litigation hold policy, somebody still might have thrown stuff out. The company had a policy not to destroy these documents.

She searched -- she -- she testified about the search that was done. They went through the search that was done. They were happy with her testimony as far as we knew. And we never heard about a complaint about any of these documents until this motion was filed.

MR. SIPES: Your Honor, may I respond for a second? Mr. Galbaith, has now several times has suggested that we brought this motion for the wrong purpose. And I just want to respond to that quickly.

This is the first time as I can recall I've ever had to bring a spoliation motion. And, candidly, have never seen anything quite like this.

THE COURT: Thank you.

MR. SIPES: It's -- it's admitted that they were anticipating litigation, consulting with lawyers and claiming work product back in 2001 and never put a litigation hold.

Now, Mr. Galbaith has represented that somehow it was understood don't destroy any mesthalime documents. Well, there's no document that suggests that There's no hold that says don't destroy mesthalime documents. And we know there are missing documents.

THE COURT: Well, we know of two. And I understand that you might not be in a position to necessarily know if there are more.

MR. SIPES: We know of more than two. We know two from the Quintiles production or at least two documents that should have been in their production that weren't. So, we know two there. We know this whole Anapharm protocol, there's no other -- there's must have been documents. But

(REDACTED)

(REDACTED)

We can surmise there are a lot of documents. You know, Judge Cavanaugh, recently in the Sinophia -- (phonetic) case in talking about Glenmark. That's another generic. They're sophisticated litigants. He said once a party reasonably anticipates litigation, it must suspend its routine document retention destruction policy and put in place a litigation hold to ensure the preservation of relevant documents. That what should have been done here.

I don't know now what was destroyed. How can we possibly know that?

THE COURT: Okay. But let's tie that into than what's sanctioned. Let's assume I find that Roxane destroyed documents or failed to have an appropriate preservation order that was -- or a litigation hold in place. And that documents were not produced that should have been.

As I sit here right now, all I have are the quintellas documents to be able to upset -- to assess their

importance. I don't have anything else. So, part of the analysis with spoliation, you have to consider the importance of this information. And so, what do I do with the fact that there's conjecture. Hey, they did it here with two out of how many documents were produced?

MR. GALBAITH: I think 80,000, Your Honor.

THE COURT: So, two that we know -- two documents are missing, 80,000 have been produced. We're assuming, and that really is all it is, we're assuming and perhaps from the scale of assumption, it's closer to the better bet that there was a protocol. But we don't know. And, by the way, even if that's so, you do have the actual testing that outlines what the

-- what steps were followed.

So, assuming I -- I agree with you, then what?

MR. SIPES: I think, Your Honor, sort of an order from least to most to try to -- I think, one thing is if they have documents that may have been destroyed on back up tapes, given that it's their failure to put in a litigation hold that has created this situation, they should search their backup tapes for responsive documents and produce those.

Because if they have them and they exist in those backup tapes, they should be required to search for it and produce them.

THE COURT: But I don't think they have backup tapes

because didn't we -- you both agree that -- you had a certain agreement with back up tapes and it's not likely that they were preserved.

MR. GALBAITH: I'm not -- I'm just not aware of that. We had an agreement that we didn't have to look at back up tapes but that's a long way from saying that we --

THE COURT: Okay. Got it. Okay. Thank you.

MR. SIPES: The next thing, I think, is you know what Judge Cavanaugh was what he called -- what's called, I think, a spoliation inference. We know there are missing documents. We cannot now know what was in them. There should at least be an inference that there were documents that were destroyed because of the failure to put a litigation hold that were relevant to the claims and defenses in the case.

(REDACTED)

Now, we don't have a lot of documents from Roxane about what they made of this. How they used this as their target. But we think that there should be an inference in this case, given that we're missing all of those documents, that -- and Roxane now, they've made this an issue. Roxane,

now in their pre-trial materials, proposes as a finding of fact, that there is no evidence that Asicol releases to the right side of the colon.

So, we think there should be an inference that A) Asicol releases to the right side of the colon, and B) that Roxane developed its product to match that release.

(REDACTED)

THE COURT: Okay. Now, I don't think I got an answer or I -- I am suffering from a lapse in memory myself.

Why does it matter which format the -- the documents that you did get in a hard copy, why does it matter? Why do you need them in an electronic format?

MR. SIPES: We believe, Your Honor, that what is missing from the electronic format is not just the documents in hard copy but maybe additional documents, as well.

THE COURT: Okay. That doesn't answer my question though.

MR. SIPES: But the fact that we didn't get them in electronic copy shows that there was wide swaths of electronic documents that were eliminated. And it was --

THE COURT: Okay. So, you don't want those documents that you have in the hard copy, you're not saying that you want them in -- in electronic copy?

MR. SIPES: Correct. Correct, Judge.

THE COURT: What you're saying is because they were produced in paper format, you have a concern coupled with these other issues. And therefore, Roxane should go back and do a search of their back up tapes.

MR. SIPES: Correct.

THE COURT: Got it. Okay.

MR. GALBAITH: Just to correct a couple of things, Your Honor.

(REDACTED)

With respect to -- to get any kind of sanction here, I believe the law is clear that there has to be some real showing of prejudice to the other side, that they didn't get something or something -- or the evidence was destroyed. They can't prove something or they won't be able to prove something.

We have on this issue that we're talking about here where this -- this product releases it's contents, we've had five experts, I believe, in this case comment on that.

They filed approximately eight expert reports on this area. **(REDACTED)** None of them have looked at any of this evidence we're talking about today. All of them have relied on experimental evidence that they have generated themselves or have been generated by other -- or that have been generated by the other side. It is all a matter of the science and of the analysis of the products themselves.

Emails here and there don't have anything to do with that issue. That's not how it's going to go down at trial. It's going to be a bunch of experts and they're all going to disagree or agree with each other. And they're all going to have different perspectives on this. But it's not going to be about what was in some protocol a decade ago.

So, they cannot prove any prejudice from the absence

of this protocol or of any of these documents or the fact that two emails were missing from one production that were found in response to a subpoena.

This is -- this is a case that's going to be proved by the experimental results because the reason for that is because when Roxane was developing this -- this product, there is no question about this. They don't dispute this.

Roxane never really examined that issue. There is no evidence, and they don't contend that there is any, that Roxane actually ever determined precisely, scientifically, how this product releases it's contents to the -- to the colon, where it releases, when it releases, the exact timing of it all.

They had guesses. They had suppositions. They had inferences. But they never did -- did that kind of experimental work.

What they did was they -- they took the product, formulated it.

(REDACTED)

There's no -- there's just no evidence in the Roxane files anywhere as to exactly how this product works. That's

why we had to do all this experimental work. That's why the parties have spent all this money, and all this effort and hired all these experts to do it. So, that's -- that's what this case is about.

It's not about what's in some email that's buried somewhere. It's not about what' in a protocol for another product.

THE COURT: I can Mr. Sipes, you're anxious. And let me have -- I'll allow you to have the last word since you're -- it's your burden.

MR. SIPES: Let me try to first address the substance so, at least, we can understand what might have been in these documents. And then I just have a few quick points.

(REDACTED)

(REDACTED)

And it couldn't be the case that they were uninterested in where their product released.

They were trying to make a product that behaved like Asicol. It is true, however, that the trail of paper documents goes cold at this point.

(REDACTED)

But yes, the paper trail goes cold at that point.

Now, the law, and for example, it's set forth in the Mosat case (phonetic) is not that we have to show what was in the documents we never got in order to show prejudice.

What we know is that in developing the product, Roxane cared very much about where their product released. They had to. They had to. They had to make a product that was going to be bioequivalent. That depended on where it released.

But we don't have those documents anymore. Yes, we have been forced to do testing, in part, to try to fill that in. But we've clearly lost a considerable amount of inquiry by Roxane on this very question.

(REDACTED)

THE COURT: Well, as I understand, and I know I said, I would let you have the last word. But that's one issue, Mr. Galbaith, that I actually hadn't seen before where if I am recalling correctly that Roxane just simply included Medeva's labeling information. I think that's what you said when you submitted your Enda and that you really didn't do any of your own testing, or something to that effect.

MR. GALBAITH: Your Honor, there's a -- there's a FDA -- the way it works is that when you file an A and DA, you are required as an initial matter to copy the brand of labeling. Okay? Your first filing is the branded label with the brands name cut up or crossed out. Sometimes, it's just done physically, "x"'d out and your own names stuck in there.

That's what goes in on the first day.

Now, as the A and DA progresses, if there is places in which you want to deviate from the branded labeling, the FDA has to authorize that. It has to approve that.

(REDACTED)

THE COURT: Well, you put in -- what did you put in your paragraph four in connection with that? Do you repeat it there, as well.

MR. GALBAITH: The paragraph four certification that goes to the FDA just says the patents invalid or unenforceable.

THE COURT: No detail.

MR. GALBAITH: Not necessarily to the FDA. But the -- what -- what goes into the -- what the FDA is interested in itself. You know you have to do certain things with respect to patents for the FDA, but the FDA doesn't look at the patents. That's -- that's up to the litigants to figure that out.

But what you have to convince the FDA of is that you're a and DA product is equivalent to the branded product. And the first thing you do, everybody does this, even if they're going to change the label, is copy the branded label. And that's what Roxane did. They copied the branded label.

And then they went back and modified it to -- to conform more with what they thought the facts would be.

(REDACTED)

THE COURT: But how do you explain on page 12 and 13 of Medeva's opening brief, the first two items in the chart that Medeva's prepared seem to be the A and DA filed with the FDA. So, that perhaps is simply Roxane cutting and pasting from Medeva's.

(REDACTED)

And so there are a number of other documents where they're talking about the release so, you -- your company -- your client actually is making some assertion about that. And

what would be the basis for that?

(REDACTED)

MR. GALBAITH: But this was their supposition about how it worked because that's how they made it and assumed it.

THE COURT: Do they always give suppositions to the FDA?

MR. GALBAITH: I don't think they -- I don't think these --

THE COURT: Well, or I'm sorry, or in your paragraph four notice, which is --

MR. GALBAITH: They give their best -- they give their best belief. They give data to the FDA and the FDA accepts it or not.

(REDACTED)

MR. SIPES: Just so we gave it to one more agency, and as a lawyer who actually does some business for FDA, you never submit something to the FDA that you don't believe. There's a criminal statute.

THE COURT: Well, I don't think Mr. Galbaith's suggesting that they didn't believe it. The question is why did they believe it.

MR. SIPES: And that's what they're suggesting is they were not concerned with where it was releasing. There's a host of documents.

(REDACTED)

That's our exhibit 26, page 162, RLI1955.

They even submitted a patent application, which, of course, was submitted under oath, in which their developers, Mr. Schlockla (phonetic) I believe was one of them, said -- described Roxane's product as delivery of the target -- of the tablet is targeted in the upper gastrointestinal tract, ug upstream of the colon. Again, that would be the terminal colon.

(REDACTED)

And as I've said, the paper trail is gone. The documents are missing. That's why we're in this boat now.

THE COURT: Okay. Thank you. Can I ask you to indulge me just for a few minutes? I want to confer with my brain trust. Make sure that I didn't miss anything and we'll be just a few minutes. And hopefully get you out of here shortly. We'll be just a few minutes.

(End of proceeding)

C E R T I F I C A T I O N

I, Lisa M. Urban, the assigned transcriber, do hereby certify the foregoing transcript of proceedings in the U.S. District Court on November 23, 2010 on CD number 11/16/09, Index Nos. 2:37 pm to 3:46 pm is prepared in full compliance with the current Transcript Format for Judicial Proceedings and is a true and accurate non-compressed transcript of the proceedings to the best of my knowledge and ability.

S/ Lisa M. Urban
LISA M. URBAN, AOC NO. 585
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Date: December 10, 2010